	For	m PTO-1449 Modified	Docket No. KLI-0002	Serial No. 09/801.470		
	(Use	of Patent and Publications Cited by Applicant several sheets if necessary)	Applicant Kliman et al.	09/801,470 RECEIV		
	Pate	Department of Commerce ent and Trademark Office	Filing Date March 8, 2001	Group TECH CENTER 160 1641 /644		
	OTH	ER DOCUMENTS (Including Autho	or, Title, Date, Perti	inent Pages, Etc.)		
PN	AA	Anderson, T. et al., "Stage specific a on endometrial epithelial cells relate 34:701-720	alterations in the anic	al membrane alvegameteine		
	AB	Bamberger, A-M. et al., "Strongly reduced expression of the cell cycle inhibitor p27 in endometrial neoplasia", <i>Virchows Arch.</i> , 1999, 434:423-28				
	AC	Beresford, S. et al., "Risk of endome combined with cyclic progestagen th 1997, 349:458-461	trial cancer in relation	n to use of oestrogen		
	AD	Bergh, P., "The impact of embryonic timing of implantation", <i>Fertil Steril</i> .	development and en , 1992, 58(3):537-54	ndometrial maturity on the		
AF		Blasco, L., "Dyssynchrony in the maturation of endometrial glands and stroma", <i>Fertil. Steril.</i> , 1994, 61(4):596-7				
	AF	Burger, C. et al., "Hormone replacement therapy in women treated for gynaecological malignancy", <i>Maturitas</i> , 1999, 32:69-76				
	AG	Bush, T., "Evidence for primary and s in women taking oestrogen replacement 17(Supplement D):9-14	secondary preventior ent therapy", <i>Eur. He</i>	1 of coronary artery disease eart J., 1996,		
	АН	Castelbaum, A., "Timing of the endor diagnosis of luteal phase deficiency",	netrial biopsy may b Fertil Steril., 61(3):4	e critical for the accurate 443-447		
	AI	Castellsague J., "Recent epidemiological studies of the association between hormone replacement therapy and venous thromboembolism", <i>Drug Safety</i> , 1998, 18(2):117-23				
AJ		Collaborative Group on Hormonal Factors in Breast Cancer. "Breast cancer and hormone replacement therapy: collaborative reanalysis of data from 51 epidemiological studies of 52 705 women with breast cancer and 108 411 women without breast cancer", <i>The Lancet</i> , 1997, 350:1047-1059.				
	AK	Creus, M. et al., "Integrin expression in normal and out-of-phase endometria", <i>Hum.</i> <i>Reprod.</i> , 1998, 13(12):3460-3468				
PN	AL	Design of the women's health initiative women's health initiative study group,	e clinical trial and ob Control Clin Trials	oservational study, The		

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r				Sheet 2 of 8		
	Form ]	PTO-1449 Modified	Docket No. KLI-0002	Serial No. 09/801,470		
	С	Patent and Publications Cited by Applicant veral sheets if necessary)	Applicant Kliman et al.	RECEIVED		
	U.S. De Patent	epartment of Commerce and Trademark Office	Filing Date March 8, 2001	Group JUN 2 6 2003 1641 JECH CENTER 1600/000		
	OTHEF	R DOCUMENTS (Including Author	r, Title, Date, Pertine	1641 TÉCH CENTER 1600/2900 nt Pages, Etc.)		
PN	AM	Dockery, P. et al., "Changes in nucl glandular epithelium in women with 11(10):2251-2256	lear morphology in the	e human endometrial		
	AN	Enders, A. et al., "Surface coats of t preimplantation period", <i>Anat. Rec.</i> ,	the mouse blastocyst ar , 1974, 180:31-46	ad the uterus during the		
	AO	Giangrande, P. et al., "The opposing the human progesterone receptor are <i>Biol.</i> , 2000, 20(9):3102-3115	g transcriptional activit	ies of the two isoforms of factor binding", <i>Mol. Cell</i>		
	AP	Gibson, M., et al., "Error in histolog component analysis", <i>Fertil Steril.</i> , 1	gic dating of secretory e 1991, 56(2):242-247	endometrium: variance		
	AQ	Grodstein, F. et al., "Postmenopausal hormone therapy and mortality", N Engl J Med, 1997, 336(25):1769-1775				
	AR	Gurpide, E. et al., "Introduction: research on the human endometrium", Ann New York Acad Sci., 1990, 622:1-5				
	AS	Hamel, P. et al., "G1 cyclins and control of the cell division cycle in normal and transformed cells", <i>Cancer Investigation</i> , 1997, 15(2):143-152				
	AT	Hendrickson, M. et al., "Surgical pathology of the uterine corpus", Major Problems Patholology, 1980, 12:36-98				
		Hewitt, K. et al., "Disappearance of anionic sites from the surface of the rat endometrial epithelium at the time of blastocyst implantation", <i>Biol Reprod</i> , 1979, 21:691-707				
	AV	Johannisson, E. et al., "Endometrial n women with regular menstrual cycles	morphology and periph s", <i>Fertil Steril.</i> , 1987,	ieral hormone levels in 48(3):401-408		
	AW .	Johannisson, E. et al., "Morphometric relation to peripheral hormone levels"	c analysis of the human	n endometrium in		
V	AX 1	Kakar, F. et al., "Non-contraceptive exwomen", Am J Public Health, 1988, 7	estrogen use and risk of			
EXAMINER		PN D	DATE CONSIDERED	D 7/15/03		

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	Form	PTO-1449 Modified	Docket No. <b>KLI-0002</b>	Serial No. 09/801,470
	(	f Patent and Publications Cited by Applicant overal sheets if necessary)	Applicant <b>Kliman et al.</b>	ECEIVE
	U.S. D	epartment of Commerce	Filing Date	JUN 2 6 2003 Group 1644 1641 TECH CENTER 1600/29
		t and Trademark Office	March 8, 2001	
PN	AY	<b>R DOCUMENTS (Including Author</b> Keller, C. et al., "Supplemental and replacement therapy", <i>J of Amer Act</i>	complementary altern	atives to hormone
	AZ	Kliman H. et al., "MAG mucin expr predict subsequent IVF failure", Soc Cincinnati (Abstr.)	ression abnormalities in	n natural cycle bionsies
J	BA Kliman, H. et al., "Absence of biochemical or morphologic markers of endometric glandular development in a mock cycle predicts pregnancy failure in a subsequent donor oocyte transfer cycle", American Society for Reproductive Medicine, 1998, San Francisco. (Abstr.)			
<b>∧</b> ,	BB	Kliman, H. et al., "A mucin-like gly golgi) antibodies", Am J Pathol, 199	coprotein identified by 25, 146(1):166-181	MAG (mouse ascites
	BC	Kumar, N. et al., "Selective down-repoorly differentiated human endome estrogen action", <i>Cancer Research</i> , 1	trial cancer cells: Impl	ne receptor isoform B in ications for unopposed
	BD	Kurman, R. et al., "Endometrial hype Blaustein's pathology of the female New York, pp. 411-437	erplasia and related cel genital tract, Ed: Kurm	lular changes" in an RJ. Springer-Verlag,
	BE	Kwon, T. et al., "Overexpression of (p27 Kip1): Effect on cell cycle reg Research Comm., 1997, 238:534-538	gulation in HeLa cells	pendent kinase inhibitors ", Biochem and Biophys
	BF	Leslie, K. et al., "Differential express receptor in human endometrial cancer 828:17-26	ion of the A and B iso r cells", <i>Ann New York</i>	forms of progesterone Acad. Sci., 1997,
	BG	Lessey, B. et al., "Integrins as marker unexplained infertility", <i>Fertil Steril.</i> ,	s of uterine receptivity 1995, 63(3):535-542	in women with primary
	BH	Lessey, B. et al., "Aberrant integrin endometriosis", J Clin Endocrinol Me	xpression in the endom	netrium of women with 649
V	BI	Lessey, B. et al., "Integrin adhesion m Correlation with the normal and abnor 90:188-195	olecules in the human	endometrium
XAMINER		PND	ATE CONSIDERED	7/15/03

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	Forn	n PTO-1449 Modified	Docket No. KLI-0002	Sheet 4 of 8 Serial No. 09/801,470		
		of Patent and Publications Cited by Applicant everal sheets if necessary)	Applicant Kliman et al.	RECEIVE		
	U.S. I Pater	Department of Commerce nt and Trademark Office	Filing Date Group TECH CENTER 160   March 8, 2001 1641 /644			
	OTHE	ER DOCUMENTS (Including Author	r, Title, Date, Pertine	ent Pages, Etc.)		
ρΝ	BJ	Li, T-C. et al., "A quantitative study comparison between women with un <i>Ob Gyn.</i> , 1990, 97:576-582	of endometrial develo	pment in the luteal phase:		
	ВК	Li, T-C. et al., "How precise is histologic dating of endometrium using the standard dating criteria?", <i>Fertil Steril.</i> , 1989, 51(5):759-763				
	BL	Li, T-C. et al., "A new method of his luteal phase", <i>Fertil Steril.</i> , 1988, 50	stologic dating of hum (1):52-60	an endometrium in the		
	BM	Lloyd, R. et al., "p27 <sup>kip1</sup> : A multifunc prognostic significance in human car	ctional cyclin-depende acers", Am J Pathol., 1	nt kinase inhibitor with 999, 154(2):313-323		
	BN	Meyer, W. et al., "Hydrosalpinges ad receptivity", <i>Human Reproduction</i> , 1	versely affect markers	s of endometrial		
	BO	Mishell, D.R., Davajan, V., and Lobo, R.A., 1991, Infertility, contraception and reproductive endocrinology, Blackwell Scientific Publications				
	BP	Morgan, D. et al., "Cyclin-dependent kinases: engines, clocks, and microprocessors", <i>Annu Rev Cell Dev Biol.</i> , 1997, 13:261-291				
	BQ	Mosher, W., "Infertility: why business is booming", Am Demograph, 1987, 9:42-43				
	BR	Mote, P. et al., "Colocalization of progesterone receptors A and B by dual immunofluorescent histochemistry in human endometrium during the menstrual cycle", <i>J. Clin. Endocrinol. Metab.</i> , 1999, 84(8):2963-2971				
	BS	Musgrove, E. et al., "Cell cycle control by steroid hormones", Sem Cancer Biol., 1994, 5:381-389				
	вт	Musgrove, E. et al., "Mechanisms of cyclin-dependent kinase inactivation by progestins", <i>Mol Cell Biol</i> , 1998, 18(4):1812-1825				
	BU	Navot, D. et al., "The window of embr conception in vitro", <i>Fertil Steril.</i> , 199	ryo transfer and the eff 1, 55(1):114-118	ficiency of human		
L	BV	Noyes, R., "Uniformity of secretory er 100 uteri removed at operation", Fertil	ndometrium: study of 1 Steril., 1956, 7:103-1	multiple sections from 09		
XAMINER	P	2W I	DATE CONSIDEREI	D # 7/15/03		

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\* A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous and easily obtainable by the Examiner

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	Form	PTO-1449 Modified	Docket No. KLI-0002	Sheet 5 of 8 Serial No. 09/801,470		
	C	Patent and Publications Cited by Applicant veral sheets if necessary)	Applicant RECE Kliman et al. JUN 2 6			
		epartment of Commerce and Trademark Office	Filing Date March 8, 2001	Groute CH CENTER 1600/2		
	OTHE	R DOCUMENTS (Including Author	r, Title, Date, Pertine			
_PN	BW	Noyes, R. et al., "Accuracy of endometrial dating", Fertil Steril., 1953, 4(6):504-517				
	BX	Noyes, R. et al., "Dating the endom	etrial biopsy", Fertil S	teril., 1950, 1(1):3-25		
	BY	Orend, G., "Cytoplasmic displacement of cyclin E-CDK2 inhibitors p21Cip1 and p27Kip1 in anchorage- independent cells", <i>Oncogene</i> , 1998, 16:2575-2583				
	BZ	Ovulation Drugs, A Guide for Patients. American Society for Reproductive Medicine, 2000, 1209 Montgomery Highway, Birmingham AL 35216-9822				
	CA	Pedersen, T., "Statin trials and goals of cholesterol-lowering therapy after AMI", Am Heart J, 1999; 138(2 Pt 2):177-82				
	СВ	Pike, M. et al., "Estrogen-progestin Natl Cancer Inst, 1997, 89(15):1110	Pike, M. et al., "Estrogen-progestin replacement therapy and endometrial cancer", J Natl Cancer Inst, 1997, 89(15):1110-1116			
	CC	Reid, I., "Pharmacological management of osteoporosis in postmenopausal women: a comparative review", <i>Drugs Aging</i> , 1999;15(5):349-363				
	CD	Reynisdóttir, I. et al., "The subcellu their inhibitory interactions with CD	lar locations of p15 <sup>ink4b</sup> DK4 and CDK2", <i>Gene</i>	and p27 <sup>Kip1</sup> coordinate s Dev., 1997, 11:492-503		
	CE	Rosano, G. et al., "Cardiovascular pharmacology of hormone replacement therapy", Drugs Aging, 1999,15(3):219-234				
	CF	Rozenberg, S. et al., "Osteoporosis Management", Int J Fertil Womens Med, 1999, 44(5):241-249				
	CG	Ross, R. et al., "Effect of hormone replacement therapy on breast cancer risk: estrogen versus estrogen plus progestin", <i>J Natl Cancer Inst.</i> , 2000, 92(4):328-332				
	СН	Rossouw, J., "Hormone replacement therapy and cardiovascular disease", <i>Curr Opin Lipidol.</i> , 1999, 10:429-434				
T	CI	Satyaswaroop, P. et al., "Isolation an Endocrinol Metab., 1979, 48(4):639-	d culture of human end -641	dometrial glands", J Clin		
XAMINER	Pat		DATE CONSIDERE	D 7/15/03		

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Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary)			Docket No. <b>KLI-0002</b>	Serial No. 09/801,470 RECEIV		
			Applicant Kliman et al.	JUN 2 6 20		
		epartment of Commerce and Trademark Office	Filing Date March 8, 2001	Group TECH CENTER 160 1641 / 644		
	OTHE	R DOCUMENTS (Including Autho	r, Title, Date, Pert	inent Pages, Etc.)		
PN	CJ	Schairer, C. et al., "Menopausal est therapy and breast cancer risk", <i>JA</i>	trogen and estrogen MA, 2000, 283(4):4	-progestin replacement 85-491		
]	СК	Scharbo-Dehaan, M., "Hormone replacement therapy", Nurse Pract. 1996, 21(12 Pt 2):1-13				
	CL	Schatz, F. et al., "Studies on human endometrial cells in primary culture", Ann New York Acad Sci., 1991, 622:80-88				
	СМ	Schneider, D. et al., "Timing of pos density: the Rancho Bernardo Study	tmenopausal estrog y", <i>JAMA</i> , 1997, 27	gen for optimal bone mineral 7(7):543-547		
	CN	Scott, R. et al., "The effect of intero on the diagnosis of luteal phase defe	bserver variation ir	a dating endometrial histology		
	СО	Seifert, M. et al., "Estrogen replacement therapy in women with a history of breast cancer", <i>Maturitas</i> , 1999, 32:63-68				
	СР	Sheaff, R. et al., "Cyclin E-CDK2 is a regulator of p27 <sup>Kip1</sup> ", Genes Devel., 1997, 11:1464-1478				
J	CQ	Shiozawa, T. et al., "Relationship be dependent kinases and sex- steroid r glands and stroma during the menstr	eceptors/Ki67 in no	ormal human endometrial		
J	CR	Shiozawa, T. et al., "Involvement of cyclin-dependent kinase inhibitor $p27^{Kip1}$ in growth inhibition of endometrium in the secretory phase and of hyperplastic endometrium treated with progesterone", <i>Mol Hum Reprod.</i> , 4(9):899-905				
	CS	Singh, S. et al., "Loss or altered subc associated adenocarcinoma", Cancer	cellular localization	of p27 in Barrett's		
	СТ	Smith, S. et al., "Endometrial biopsy on clinical practice", <i>J Repro Med.</i> , 1	dating: interobserv			
ł	CU	Society for assisted reproductive tech Disease Control, Atlanta, GA (The re Control's web site at: <u>http://www.cdc</u> the direct cite to the PDF file)	nology 1997 natio	ed at the Centers for Disease		

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\* A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous and easily obtainable by the Examiner

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	Form	PTO-1449 Modified	Docket No. KLI-0002	Serial No. 09/801,470		
	C	Patent and Publications Fited by Applicant Veral sheets if necessary)	Applicant Kliman et al.	· · · · · · · · · · · · · · · · · · ·		
		epartment of Commerce and Trademark Office	Filing Date March 8, 2001	Group 1641		
	OTHE	R DOCUMENTS (Including Author	, Title, Date, Pertine	nt Pages, Etc.)		
PN	CV	Soucek, T. et al., "Inactivation of th loss of the tuberous sclerosis compl 95:15653-15658	e cyclin-dependent kir	ase inhibitor p27 upon		
	CW	Tang, M-X. et al., "Effect of oestrog Alzheimer's disease", <i>The Lancet</i> , 1	gen during menopause 996, 348(9025):429-4	opause on risk and age at onset o ):429-432		
	СХ	Tavani, A. et al., "The adverse effect 1999,14(5):347-357	ects of hormone replacement therapy", Drugs Aging			
	СҮ	Taylor, H. et al., "HOXA10 is expre implantation in the human endometr	essed in response to ser ium", J Clin Invest., 1	x steroids at the time of 998, 101(7):1379-1384		
	CZ	Third Party Reproduction, A Guide for Patients. American Society for Red Medicine. 1996. 1209 Motgomery Highway, Birmingham AL 35216-982				
	DA	Treloar, A. et al., "Variation of the human menstrual cycle through reproductive life", <i>Internat J Fertil.</i> ,1967, 12(1, pt. 2):77-126.				
	DB	Vassilopoulou-Sellin et al., "Estroge cancer: clinical outcome of 319 won 1999, 17(5):1482-1487	n replacement therapy nen followed prospecti	after localized breast vely", <i>J Clin Oncol</i> ,		
	DC	Vassilopoulou-Sellin et al., "Random therapy in women with a history of b 1994, 16:153-159	nized prospective trial preast cancer", <i>J of Nat</i>	of estrogen-replacement I Cancer Inst Monog.,		
	DD	Wang, H. et al., "Progesterone recep human endometrial stroma", Mol. Hu	tor subtype B is differed um. Reprod., 1998, 4(4	entially regulated in ):407-412		
* ¥	DE	Yen, S.S.C., Jaffe, R.B., and Barbier physiology, pathophysiology, and cli	i, R.L., 1999, Reprodu nical management. W	ctive endocrinology: .B. Saunders Company		
EXAMINER		will not be forwarded to the U.S.	DATE CONSIDERE			

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\* A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous and easily obtainable by the Examiner

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	Form	n PTO-1449 Moo	lified	Docket No. KLI-0002	Serial N 09/801,4	
List of Patent and Publications Cited by Applicant (Use several sheets if necessary)			Docket No.Serial No.KLI-000209/801,470ApplicantRECEIVKliman et al.JUN 2 6 20			
	U.S. I Pater	Department of Comr at and Trademark Of	nerce ffice	Filing Date GroupECH CEN   March8, 2001 1641 644		CH CENTER 1600, 44
		U	. S. PATENT I	OCUMENTS		
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